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Statement before the Transmissible Spongiform Encephalopathy Advisory Committee October 14, 2004

G. Michael Fitzpatrick, Chief Policy Officer

America's Blood Centers (ABC) is a national network of locally-controlled, non-profit community blood centers that provide nearly half of the U.S. blood supply from volunteer donors. Collectively, ABC total blood collections exceeded 7 million donations in 2003. ABC members operate in 45 states and in Quebec, Canada, and serve more than half of the 6,000 hospitals in the U.S.

It has been almost 8 years since the implementation of safeguards to protect the bovine and human ends of the food chain from Bovine Spongiform Encephalopathy (BSE) and the human form variant Creutzfeldt-Jacob Disease (vCJD). The FDA announced donor deferral criteria in August of 1999 (five years ago) based on the application of the Precautionary Principle and the hypothesis that the prion responsible for vCJD could be transmitted by transfusion.

Two cases of vCJD have been associated with the transfusion of blood from individuals who later died from vCJD. This causal relationship is based on mathematical models of probability, not biological data. The lack of biological data continues to confound the issue and our donors. However, we must note that the identification of these two cases has not changed the picture. The world is not different than it was six months ago. Five years ago the FDA developed a model based on potential exposure to the vCJD agent. This model continues to be used to defer thousands of donors who do not understand why they are being deferred when it appears that both the human and bovine epidemics are over. The toll of the human epidemic currently stands at 157 diagnosed cases since 1994. There has only been one new human case in the past year.

We believe it is time to begin the discussion of an exit strategy for this deferral. Immense resources (people and dollars) continue to be used to update deferral questions, screen and defer donors, and respond to questions from deferred donors and their friends. These resources could be better utilized in cGMP compliance and developing new screening techniques, better procedures, and recruitment of new donors. One severely affected population is the dependents of the military stationed in Europe during the 1980 to 1996 risk period. Many are just now achieving the age of donation and, like my own daughter who was born in Germany in 1988 lived there for two years as an infant eating formula and baby food, are indefinitely deferred. During the rollout of the Ad Council campaign on Capitol Hill a young staffer who was a teen in Europe stationed there with her parents asked if she would ever be able to donate.

We propose that FDA initiate discussions of what would constitute an exit strategy. The questions that need to be asked are: What requirements should be fulfilled before discontinuance of part or all vCJD deferrals? For instance, would we consider discontinuing the UK deferrals a certain number of years after implementation of recognized safety measures? Could we decide that former US military and dependents have had less exposure than originally thought to the vCJD agent and should be deferred for a shorter period of time? Could we discuss the possibility of removing countries which had no human cases of vCJD (all but France and Italy) from the deferral criteria?

Thank you for the opportunity to address the committee and we hope to be able to work with the FDA in the future on determining an appropriate exit strategy.

Written Submissions Received
For TSEAC
October 14, 2004

1. First submission (redacted) concerning a patient

Please could you submit the following (3 pages detailing specific questions for the meeting on BSE/ v CJD on the 14th Oct. and a copy of a letter to my husband's consultant re vCJD which may be of interest to members of the committee -

2. Second submission from Terry S. Singletary
3. Third submission from Ms. Sachau